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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,926	12/08/1999	BURTON G. CHRISTENSEN	P-061-R2	8221

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WASHINGTON, DC 20005

EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/457,926	<b>Applicant(s)</b> CHRISTENSEN ET AL.	
	<b>Examiner</b> Mark Shibuya	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-46, 49-51, 53-55, 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-46, 49-51, 53-55, 57, and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 41-46, 49-51, 53-55, 57, and 58 are currently pending in the examination.

### ***Maintained Claim Rejections***

#### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 41-46, 49-51, 53-55, 57, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection maintains the reasons of record as set forth in the previous Office action mailed 11/17/2003.

### ***Response to Arguments***

3. Applicant states, in the Reply, filed 4/12/2004, to the previous Office action, at p. 5, that the examiner asserts that applicant's specification does not enable one of skill in the art to use the claimed invention because of the lack of working examples and applicant's statements regarding prior art references previously relied upon in a now-withdrawn rejection under 35 U.S.C. § 103(a).

Applicant, at p. 3, para 3, asserts that the examiner's statement that the scope of the claims represents broad scope fails to take into account the numerous limitations cited in the present claims. Applicant at p. 4, para 2, states that the enablement requirement of 35 U.S.C. § 112, first paragraph, does not require working examples. Applicant, at pp. 4-5, offered six instances of how the specification contains sufficient information regarding the subject matter of the claims as to enable the practitioner to make and use the claimed invention. The applicant, at pp. 5-6, asserts that the specification therefore provides a large amount of direction by the inventors, as well as numerous examples.

Applicant, at p. 6, para 2, requests that the examiner provide support for the "unsubstantiated conclusion that the antibacterial testing is 'non-routine.'" Applicant, at p. 6, para 3, argues that the prior art publications cited by the examiner shows what was known *before* the claimed invention; in contrast, applicant's specification provides sufficient guidance to the practitioner to make and use the claimed invention.

4. Applicant's arguments filed 4/12/2004 have been fully considered but they are not persuasive.

Applicant's argument that the specification provides sufficient guidance and direction to enable one of skill in the art to use the claimed invention is not persuasive because the cited prior art publications indicate that the art is unpredictable, and the specification's disclosure does not overcome the unpredictability of the art.

Applicant states that the specification teaches an (1) exhaustive description of the compounds; (2) Synthetic Examples 1-13 directed to formation of numerous compounds of the claimed invention, (specification at pp. 116-127); (3) a detailed description of the forms of the pharmaceutical compositions, (specification at pp. 112-115); and (4) Formulation Examples 1-10 describing forms of the compositions, (specification at pp. 127-132): The aforementioned disclosures from the specification teach how to make the invention, but do not teach how to use the invention for antibacterial activity. The (5) disclosure of standardized testing, (specification at p. 112) and the (6) Biological Examples regarding testing of the compounds, (specification at pp. 132-134) are prophetic and not working examples. Thus, nowhere does the specification actually show antibacterial activity using the claimed invention.

Support for the conclusion that the antibacterial testing is "non-routine" has been shown by the cited publication of the Physicians Desk Reference, 53<sup>rd</sup> Edition, 1999, p. 1133, which states that solutions of vancomycin exhibit a physical incompatibility when mixed a number of drugs, including ceftazidime", (a lactam). Furthermore, the cited reference of Boeckh, at p. 93, shows that when vancomycin and ceftazidime (not linked) are used in combination, flexibility in dosing is required in order to effectively treat certain types of bacterial infections. In contrast, the cited reference of Truett, at col. 1, lines 47-50, col. 5, lines 42-60, col. 22, line 11-col. 25, line 14, col. 25, line 19-col. 31, line 52, and col. 45, lines 26-63, does not require that flexibility, but instead is limited to the preparation of compounds containing a 1:1 ratio of linked, (non-lactam comprising) antibiotic

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moieties. The irreconcilability of the above teachings indicate the unpredictable nature of the art. See, also, pages 21-25 of applicant's Reply, filed 7/15/2003, to the Final Rejection, mailed 7/2/2002 (showing unpredictability of antibacterial art).

Applicant argues that the cited art publications were not indicative of the state of the art because the specification itself makes the art predictable. The specification does not itself teach working examples. It is true that working examples are only one of the factors to be considered in establishing enablement of the claimed invention. However, the specification does not provide guidance and direction that overcomes the unpredictability of antibacterial activity using the linked compounds of the invention. Applicant's argument seeks to bootstrap the specification into a disclosure that overcomes the art recognized unpredictability of antibacterial activity using the claimed invention, as shown by aforementioned publications, without an actual teaching, anywhere in the specification, of such antibacterial activity. Therefore, undue experimentation would continue to be required of one of skill in the art to use the claimed invention.

### ***Conclusion***

5. Claims 41-46, 49-51, 53-55, 57, and 58 stand finally rejected.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Shibuya  
Examiner  
Art Unit 1639

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**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
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